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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,241	10/23/2000	Nicole Barie	K 168	9230

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/15/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/694,241

Applicant(s)

BARIE ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 2-5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, the parent claim, claim 1, already recites that the photolinker is T-BSA. Claims 2 and 3 recite that the photolinker is TRIMID modified, but this limitation is inherent in the recitation of T-BSA (TRIMID modified BSA). Claim 4 recites that the photolinker is aminodextran, but claim 1, on which claim 4 ultimately depends, already recites T-BSA as the linker. Claim 5 recites BSA as the photolinker, but T-BSA has already been recited in the parent claim.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation of “a T-BSA photolinker”. With this recitation, it is unclear of T-BSA is a class of photolinkers or one specific photolinker. In addition, applicant should not use an abbreviation when referring to the photolinker.

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5. Claim 3 recites the limitation of a TRIMID-modified polysaccharide. There is insufficient antecedent basis for this limitation in the claim. This terminology does not appear anywhere in the specification to provide adequate support for this limitation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Chai-Gao et al. (US Pat. 5,858,802).

Swan et al. teach a process for the preparation of crosslinked matrices containing covalently immobilized chemical species and unbound releasable chemical species. According to the reference, polymers may be covalent immobilized in an insoluble 3-D crosslinked matrix, which is preferably formed as a coating upon a surface. A desired chemical species and a polymeric coupling compound such as a photoderivatized polymer having multiple photoreactive groups are brought into proximity to each other. Upon activation, bonding occurs (abstract and cols. 2-3). Dextran may be the polymer from which the coupling compound is derived (col. 3, line 62). In addition, the photoreactive groups of the reference may be diazirines, such as 3-trifluoromethyl-3-phenyldiazirine (col. 5, line 55).

Hubbell et al. teach interfacial polymerization to form a membrane on the surface of a biological membrane. Tissue is directly coated with photoinitiator, which is immersed in macromer solution, and immediately irradiated. This results in a thin polymer coat (col. 9). Dextran may be the macromer of the reference (col. 11, lines 19-54). However, neither Swan et al. nor Hubbell et al. teach the use of TRIMID modification or T-BSA.

Chai-Gao et al. teach a method for making a device including a substrate and at least one biologically active substance bound to the surface of the substrate. The device is obtained by simultaneous or sequential reaction of the substrate and of the substance with a bifunctional coupling agent in which one of the functional groups may be photoactivated. The photoactivator is preferably a TRIMID-modified protein, such as T-BSA (cols. 3-5).

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator of Chai-Gao et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Chai-Gao et al. as the photoinitiator, with the only difference being that the diazirine in Chai-Gao et al. is substituted. Since the diazarines of Chai-Gao et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazarine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would have further been obvious to use aminodextran instead of dextran as the polymer because the two molecules differ only by 1 substitution, which is not viewed as detrimentally altering the binding capability of the dextran.

10. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Wessa et al. (WO 97/43631)

Swan et al. and Hubbell et al. teach coating processes, as previously discussed. However, the references do not teach TRIMID modification, the use of BSA or polyimide, or application to biological sensors.

Wessa et al. teach a process for producing a sensor for detecting proteins. The sensor consists of a sensor body, one surface of which is coated with a polymer layer with receptor molecules bonded to said polymer layer. The bond between the polymer and the receptor molecules is provided by a photoreactive molecule that is covalent to the lysine of a receptor molecule and inserted into the polyimide. The photoreactive molecule is preferably TRIMID. The modified protein, which may be T-BSA, is bound to the polymer layer by UV irradiation. The sensor of the reference may be used as a surface acoustic wave sensor, which is interpreted

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as an electromechanical sensor. In addition, wave sensors are also interpreted as mass sensitive, as a difference in mass on the sensor will affect the results in some manner.

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator and polyimide of Wessa et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Wessa et al. as the photoinitiator, with the only difference being that the diazirine in Chai-Gao et al. is substituted. Since the diazarines of Wessa et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazarine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would have further been obvious to use aminodextran instead of dextran as the polymer because the two molecules differ only by 1 substitution, which is not viewed as detrimentally altering the binding capability of the dextran. In addition, it would have been obvious to apply the modified coating process of Wessa et al. and Swan et al. or Hubbell et al. to a biological sensor, as surface receptors are commonly used in sensing applications.

Response to Arguments

11. Applicant's arguments filed July 7, 2002 have been fully considered but they are not persuasive.

12. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of unmodified dextran, the binding of a biologically active material to the surface without being enclosed in a matrix, and the reaction of a biologically active material with a reactant for detection purposes) are not recited in the rejected claim(s). Although the claims are interpreted

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in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

13. Applicant's arguments with respect to claims 2-5 and 7-10 (rejections under 35 USC 103) are based on the premise that the references applied under 35 USC 102 were insufficient.

However, applicant's amendments necessitated the application of the Swan and Hubbell references under 35 USC 103, and their combination with Chai-Gao and Wessa are deemed to render the claimed invention obvious for reasons discussed above under the heading of 35 USC 103.

14. Applicant's arguments with respect the advantages of the present invention over the prior art are moot, as they rely on a feature (unmodified dextran) that has not been claimed.

Conclusion

Claims 1-10 are rejected.

References: The Sigrist et al. references are cited as art of interest for teaching the immobilization of mixtures of dextran and photolinkers on surfaces.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

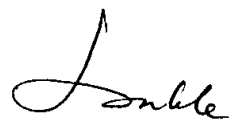
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1461

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July 12, 2002


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
07/12/02